

In the Claims

This listing of claims will replace all prior versions and listings of claims in this application.

1 (Currently amended). An endogenous material, inducible in a mammal post-oestrus by clomiphene, and having the ability to reduce the mass of body organs including non-gonadal organs, of a live adult mammal, the material being obtained by:

collecting ovarian venous blood from a female mammal post-oestrus;

preparing ovarian venous plasma from the blood; and

at least partially purifying said material from the plasma to obtain at least a nominal 10-30 kD sub-fraction; and wherein said material has a specific activity of at least 1 unit/ml, wherein a unit is defined as an amount of the material which, when administered daily, is sufficient to decrease the relative (post-exsanguination) organ weight of a female rat heart by 5% when administered in 4 equal daily doses.

2 (Cancelled).

3 (Previously presented). The material according to claim 1, wherein the purifying comprises obtaining a 10-20 kD fraction.

4 (Previously presented). The material according to claim 3, wherein the purifying additionally comprises ion exchange chromatography, and collecting the fraction eluted in 0.1-0.2 M NaCl.

5 (Previously presented). The material according to claim 1, wherein the purifying comprises the following protocol:

clearing plasma by centrifugation;

spinning the cleared plasma to give a nominal 0-30 kD fraction;

spinning the nominal 0-30 kD fraction to give the nominal 10-30 kD sub-fraction;

concentrating and gel-filtering the nominal 10-30 kD sub-fraction to give a nominal 10-20 kD sub-fraction;

concentrating and buffer-diluting the nominal 10-20 kD sub-fraction repeatedly;

applying the concentrate and buffer-diluted nominal 10-20 kD sub-fraction repeatedly to an ion exchange column eluted with a gradient of 0-3 M NaCl; and

dividing the eluate into 0-0.1 M, 0.1-0.2 M and 0.2-0.3 M NaCl ion exchange fractions.

6 (Previously presented). The material according to claim 1, wherein the mammal is a sheep.

7 (Canceled).

8 (Previously presented). A pharmaceutical composition comprising an endogenous material inducible by clomiphene, having the ability to reduce the mass of body organs including non-gonadal organs, the material being obtained by:

collecting ovarian venous blood from a female mammal;

preparing ovarian venous plasma from the blood; and

at least partially purifying said material from the plasma to obtain at least a nominal 10-30 kD sub-fraction

and a pharmaceutically acceptable excipient or carrier.

9 (Canceled).

10 (Canceled).

11 (Previously presented). The pharmaceutical composition, according to claim 8, wherein the purifying comprises obtaining the 10-20 kD fraction.

12 (Previously presented). The pharmaceutical composition, according to claim 8, wherein the purifying additionally comprises ion exchange chromatography, and collecting the fraction eluted in 0.1-0.2 M NaCl.

13 (Previously presented). The pharmaceutical composition, according to claim 8, wherein the purifying comprises the following protocol:

clearing plasma by centrifugation;

spinning the cleared plasma to give a nominal 0-30 kD fraction;

spinning the nominal 0-30 kD fraction to give the nominal 10-30 kD sub-fraction;

concentrating and gel-filtering the nominal 10-30 kD sub-fraction to give a nominal 10-20 kD sub-fraction;

concentrating and buffer-diluting nominal 10-20 kD sub-fraction repeatedly;

applying the concentrated and buffer-diluted nominal 10-20 kD sub-fraction repeatedly to an ion exchange column eluted with a gradient of 0-3 M NaCl; and

dividing the eluate into 0-0.1 M, 0.1-0.2 M and 0.2-0.3 M NaCl ion exchange fractions.

14 (Previously presented). The pharmaceutical composition, according to claim 8, wherein the mammal is a sheep.

15 (Withdrawn). A method for treating organ or tissue hypertrophy wherein said method comprises administering, to a patient in need of such treatment, an effective amount of an endogenous material, inducible by clomiphene, having the ability to reduce the mass of body organs including non-gonadal organs, the material being obtained by:

collecting ovarian venous blood from a female mammal;

preparing ovarian venous plasma from the blood; and

at least partially purifying said material from the plasma to obtain at least a nominal 10-30 kD sub-fraction.

16 (Canceled).

17 (Withdrawn). The method, according to claim 15, wherein the purifying comprises obtaining the 10-20 kD fraction.

18 (Withdrawn). The method, according to claim 15, wherein the purifying additionally comprises ion exchange chromatography, and collecting the fraction eluted in 0.1-0.2 M NaCl.

19 (Withdrawn). The method, according to claim 15, wherein the purifying comprises the following protocol:

clearing plasma by centrifugation;
spinning the cleared plasma to give a nominal 0-30 kD fraction;
spinning the nominal 0-30 kD fraction to give the nominal 10-30 kD sub-fraction;
concentrating and gel-filtering the nominal 10-30 kD sub-fraction to give a nominal 10-20 kD sub-fraction;
concentrating and buffer-diluting the nominal 10-20 kD sub-fraction repeatedly;
applying the concentrated and buffer-diluted nominal 10-20 kD sub-fraction repeatedly to an ion exchange column eluted with a gradient of 0-0.3 M NaCl; and
dividing the eluate into 0-0.1 M, 0.1-0.2 M and 0.2-0.3 M NaCl ion exchange fractions.

20 (Withdrawn). The method, according to claim 15, whercin the mammal from which the ovarian venous blood is collected is a sheep.

21 (Withdrawn). The method, according to claim 15, wherein the patient is in need of treatment for the group consisting of prostatic hypertrophy, cardiac hypertrophy, polycystic ovarian syndrome, endometriosis, polycystic renal disease, and pituitary adenoma.

22 (New). A purified endogenous material, inducible in a mammal post-oestrus by clomiphene, and having the ability to reduce the mass of body organs including non-gonadal organs, of a live adult mammal, the material being obtained by:

collecting ovarian venous blood from a female mammal post-oestrus;

preparing ovarian venous plasma from the blood; and

at least partially purifying said material from the plasma to obtain at least a nominal 10-30 kD sub-fraction; and further purifying the material utilizing one or more of the following: HPLC, FPLC, gel filtration, electrophoresis, column chromatography, ion exchange chromatography, isoelectric focusing and immuno-affinity columns.